510(k) SUMMARY

JAN 0 3 2013

Submitted By: Jennifer Richardson, MA
Cook Incorporated
750 Daniels Way
Bloomington, IN 47404

Device:

Trade Name: Retracta™ Detachable Embolization Coil
Proposed Classification: Device, Vascular, For Promoting Embolization
KRD (21 CFR §870.3300)

Indications for Use:

Retracta™ Detachable Embolization Coils are intended for arterial and venous embolization in the peripheral vasculature.

Predicate Device:

The Retracta™ Detachable Embolization Coil is identical in terms of intended use, and similar in terms of principles of operation, materials of construction, and technological characteristics to the predicate devices. The device, subject of this submission, is substantially equivalent to the MReye Flipper® Detachable Embolization Coils and the Detach 11™ and Detach 18™ Embolization Coils cleared under 510(k) numbers K063619 and K992121, respectively.

Comparison to Predicate Device:

It has been demonstrated that the Retracta™ Detachable Embolization Coil is comparable to the predicate devices. The predicate devices and the device subject of this submission are all intended for arterial and venous embolization in the peripheral vasculature. The predicate and proposed devices consist of a fibered metallic implant that causes embolization by mechanically obstructing the vessel and causing thrombogenesis. The predicate devices and proposed devices have delivery wires that detach from the embolization coils via a screw-like mechanism.

Device Description:

The Retracta™ Detachable Embolization Coil consists of a fibered embolization coil constructed of platinum and a detachable delivery system. The implant consists of coiled wire and synthetic fibers which increase thrombogenesis. Embolization fibers are spaced along the coil until nearly the proximal tip. The fibers extend perpendicular to the long axis of the coil. Once deployed, the coil forms a curl, which varies in curl diameter and

spacing. The embolization coil is delivered to the vasculature by means of a coil delivery wire.

Test Data:

The following tests were performed to satisfy the FDA *Guidance for Industry and FDA Staff: Class II Special Controls Guidance Document: Vascular and Neurovascular Embolization Devices* (2004) and to demonstrate that the Retracta™ Detachable Embolization Coil meets applicable design and performance requirements and supports a determination of substantial equivalence.

- Tensile Testing – Testing shows the tensile strength during proper clinical use should not fracture the delivery system. Testing demonstrated that the delivery system met all predetermined acceptance criteria.
- Device Migration Testing – Testing shows that during proper clinical use devices should not migrate or perforate vessels. Testing demonstrated that the device met the predetermined acceptance criteria.
- Load to Retract Testing – Testing shows that under normal clinical use of the device the load to retract the coil into the delivery system after deployment was less than 4 Newtons. The device met the predetermined acceptance criteria.
- Corrosion Testing – The device demonstrated sufficient resistance to corrosion.
- MRI Testing – MRI testing verifies that the implant will be marked as MR conditional with the applicable parameters listed in the Instructions for Use.
- Radiopacity Comparison Testing – Platinum coils have the highest visibility in radiopacity testing when compared with other metallic coils.
- Biocompatibility Testing – Testing shows the device is biocompatible. In conformance with the applicable sections of ISO 10993-1, the predetermined acceptance criteria were met.

The results of these tests provide reasonable assurance that the device has been designed and tested to assure conformance to the requirements for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Cook Incorporated
c/o Ms. Jennifer Richardson, MA
Regulatory Affairs Specialist
750 Daniels Way
Bloomington, IN 47404

JAN 0 3 2013

Re: K123712
Trade/Device Name: Retracta™ Detachable Embolization Coil
Regulation Number: 21 CFR 870.3300
Regulation Name: Vascular Embolization Device
Regulatory Class: Class II
Product Code: KRD
Dated: December 03, 2012
Received: December 04, 2012

Dear Ms. Richardson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Matthew G. Hillebrenner

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123712

Device Name: Retracta™ Detachable Embolization Coil

Indications for Use for the Retracta™ Detachable Embolization Coil:

The Retracta™ Detachable Embolization Coil is intended for arterial and venous embolization in the peripheral vasculature.

Prescription Use __XX__ OR Over-the-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K123712